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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Manal Yousof, Quality Assurance & Regulatory Affairs Manager

New Device Name:

Trade/Proprietary Name:	EQUAL Dose 4.0
Common/Usual Name:	Radiation Therapy Verification Tool
Classification Name:	System,Planning,Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

Legally Marketed Device(s)

Our new device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	TMS v5.1	K010682
Nucletron BV	EQUAL Dose 1.0	K073273

Description:

MUV 4.0 is a quality assurance (QA) tool intended for independent verification of the dose calculations performed during treatment planning for external beam therapy. The intended user is a medical physicist or someone well familiar with the dosimetric concepts that are of importance in external beam therapy.
The software requires beam data for individual treatment plans to be imported through the DICOM RT Plan format. The parameters associated with the treatment delivery on the accelerator can not be edited within the software, although parameters related to the calculation inside the patient/phantom, such as the coordinates and depths of the calculation points, are open for editing.

The software is validated for broad megavoltage photon beams in the range from 4 up to 30 MV and broad electron beams from 4 to 30 MeV, delivered by standard medical linear accelerators (linacs).

The software runs on a Windows XP, windows Vista and windows 7 systems (32 bit)

Intended use:

The legally marked predicate device (K073273) has the same intended use as the new device cited:

Equal Dose 4.0
Equal Dose 4.0 is a quality assurance (QA) tool intended for independent *verification* of the dose calculations performed during treatment planning for external beam therapy.

The intended user is a medical physicist or someone well familiar with the dosimetric concepts that are of importance in external beam therapy.

- Cleared EQUAL Dose1.0 K073273 → same intended use and intended user

Summary of technological considerations:

- Cleared (TMS v5.1) K010682 → Treatment Planning Method: External Beam
  - Treatment modalities: Photon beams and electron beams
  - Dose Calculation:
    - Photons: Collapsed Cone or Pencil Beam algorithm
      Electrons: Gaussian Pencil Beam
  - Dimension: 3D

- Cleared EQUAL Dose1.0 K073273 → Treatment Planning Method: External Beam
  - Treatment modalities: Photon beams
  - Dose Calculation:
    - Photons: Pencil Beam algorithm
  - Dimension: Point Calculation

(EQUAL Dose) 4.0 (not applicable)	• Treatment Planning Method: External Beam • Treatment modalities: Photon beams and electron beams • Dose Calculation: • Photons: Pencil Beam algorithm Electrons: Gaussian Pencil Beam • Dimension: Point Calculation

The cleared device TMS v5.1(K010682)has a wider Scientific Technology than the new device "EQUAL Dose 4.0". The new device is merely a *verification* tool while TMS v5.1 is a complete treatment planning system

Name: John Lapre
Title: Vice President Research & Development
Nucletron B.V.
Veenendaal, The Netherlands

Sept. 20, 2010
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Manal Yousof
Quality Assurance and Regulatory Affairs Manager
Nucletron Corporation
7021 Columbia Gateway Drive, Suite 200
COLUMBIA MD 21046

SEP 15 2011

Re: K103515
Trade/Device Name: EQUAL Dose 4.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: July 29, 2011
Received: July 29, 2011

Dear Mr. Yousof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number	K103515
Device Name	EQUAL Dose 4.0
Indications for Use	MUV 4.0 is a quality assurance (QA) tool intended for independent verification of the dose calculations performed during treatment planning for external beam therapy. The intended user is a medical physicist or someone well familiar with the dosimetric concepts that are of importance in external beam therapy.

Prescription Use ___X___ (Part 21 CFR 801 subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103515